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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,969	07/21/2005	Tomoharu Suga	236276-000003	2010
84310	7590	03/31/2011	EXAMINER	
Troutman Sanders LLP The Chrysler Building 405 Lexington Avenue New York, NY 10174			AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			03/31/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/542,969

Applicant(s)

SUGA ET AL.

Examiner

HASAN AHMED

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment and remarks, filed on 7 January 2011.
- Applicants' remarks have been considered but are moot in view of the new ground of rejection.

* * * * *

Status of the Claims

Claim 1 is cancelled. Claims 2-10 are rejected.

* * * * *

Claim Interpretation

Independent claim 6 has been amended to claim an intraorally rapidly disintegrating tablet which comprises an active ingredient mixed with at least one sugar to form a core and a coating of a starch substantially completely covering said core to form a granule. Independent claim 7 differs from independent claim 6 sugar is not explicitly listed as an ingredient that is added to the core.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 361 874 ("KOYAMA") (see IDS filed on 21 July 2005).

KOYAMA discloses rapidly disintegrating spherical granules (see, e.g., page 2, line 38). The core of the granules may be comprised of sucrose (see page 2, line 53) and an active agent (see page 2, line 54) and coated with corn starch (see page 2, line 53), reading on claims 2, 3, and 6-8. The granules are spray coated with low substituted hydroxypropyl cellulose (see, e.g., page 2, line 39), and optionally, additives such as corn starch (see page 3, line 23) reading on claims 2, 6, 7, and 8. It is noted that independent claims 6 and 7 are constructed with the open transition phrase "comprising"; as such, the claims do not preclude ingredients which are not explicitly claimed.

KOYAMA uses a CF granulator in a granulation process to spray the coating solution onto the core to form a coating (see page 2, lines 39-43). Such a process inherently results in substantially complete covering of a core to form a granule, reading on claims 6 and 7. The disclosed disintegrating agent coated granules may be compressed into tablets with a thickness of 8.4 mm (see Example 2), reading on claims 5-7 and 10.

Regarding claim 7, while KOYAMA does not disclose a core comprising active agent alone, the core disclosed by KOYAMA reads on claim 7 as currently constructed because claim 7 uses the open transition phrase "comprising" and thus does not preclude inclusion of agents other than a water soluble active ingredient (such as sucrose) to the claimed core.

Regarding the limitation "intraorally rapidly disintegrating tablet", as currently claimed, applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. *In re Fitzgerald*, 205 USPQ 594.

Regarding claims 4 and 9, KOYAMA teaches a particle size between 12 (1,400 micrometers) and 32 (500 micrometers) mesh (see, e.g., page 3, line 57). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose an intraorally rapidly disintegrating tablet which comprises an active ingredient mixed with at least one sugar to form a core and a coating of a starch completely covering said core to form a granule, as taught by KOYAMA. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in granules with increased granule strength and rapid disintegration, as explained by KOYAMA (see page 2, line 38).

* * * * *

Conclusion

Applicants' amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615